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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial, Ltd. The supplemental NADA provides for the addition of several new species of internal parasites to product labeling for ivermectin paste for horses. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 134–314 for EQVALAN (ivermectin) Paste for Horses. The supplemental application provides for the use of ivermectin paste for the treatment and control of *Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocyclus* spp., including: *C. coronatus*, and *C. labratus*. Also, the label descriptions of some currently-approved parasite genera are being revised to add included species for which

NFR 1

data already exists in the NADA file and to reflect changes in scientific nomenclature. The supplemental NADA is approved as of April 2, 2003, and 21 CFR 520.1192 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR part 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning April 2, 2003. This marketing exclusivity only applies to the parasites for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520–ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1192 is amended by revising paragraphs (a) and (b); by redesignating paragraph (d) as paragraph (e); by adding new paragraph (d); by removing the last sentence of newly redesignated paragraphs (e)(1)(iii) and (e)(2)(iii); by redesignating new paragraph (e)(1)(ii) as paragraph (e)(1)(ii)(B); in newly redesignated paragraph (e)(1)(ii)(B) by removing "spp." after "Onchocerca"and by adding in its place "sp."; and by adding new paragraph (e)(1)(ii)(A) to read as follows:

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 050604 for use of a 1.87-percent paste as in (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section and a 0.153-percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311 and 059130 for use of a 1.87-percent paste for use as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

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(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use*—(A) For treatment and control of large strongyles (adults) (*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp., including *T. brevicauda* and *T. serratus*; and *Craterostomum acuticaudatum*); small strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) (*Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; and *Petrovinema poculatum*); pinworms (adults and fourth-stage larvae) (*Oxyuris equi)*; ascarids (adults and third- and fourth-stage larvae) (*Parascaris equorum*); hairworms (adults) (*Trichostrongylus axei*); large-mouth stomach worms (adults) (*Habronema muscae*); bots (oral and gastric stages) (*Gasterophilus* spp., including *G. intestinalis* and *G. nasalis*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

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Dated: July 8, 2003

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